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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,791	03/21/2002	Christoph Bittner	20908.002US	9539
22870	7590	10/20/2004	EXAMINER	
TECHNOPROP COLTON, L.L.C.			HANLEY, SUSAN MARIE	
P O BOX 567685			ART UNIT	PAPER NUMBER
ATLANTA, GA 311567685			1651	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,791	Applicant(s) BITTNER, CHRISTOPH	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-21 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

The examiner for this application has been changed to Susan Hanley. Her contact information appears at the end of this Office Action.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9 and 22-24, in the reply filed on 7/14/04 is acknowledged. The traversal is on the ground(s) that the claimed inventions are not independent and distinct as discussed by the MPEP in 802.01 and 808.01. Applicant further argues that the PTO has failed to indicate whether the two groups of claims have different US classifications. Applicant further asserts that the PTO has not shown distinctness between the apparatus and the method of using said apparatus as discussed in the MPEP 806.05(e). Applicant alleges that the PTO did not establish any lack of an inventive step and has not complied with the MPEP guidelines concerning the relatedness of the two inventions as in MPEP 806.05(e). Applicant states that the apparatus is used to carry out the claimed method and there is unity of invention. Applicant argues that the apparatus is not capable of being used without the claimed method and that they should be considered as one and the same invention.

This is not found persuasive because Applicant has responded to the restriction requirement as if the restriction requirement had been made under 35 USC 121. However, this application is a 371 of PCT/EP00/10030 and was restricted properly under the provisions of 35 U.S.C. 121 and 372 which require restriction when the application contains the inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In the restriction requirement, it was explained that the apparatus and the method do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because the apparatus is known in the prior art (US 4,810,487) and therefore does not provide a contribution over the art. Thus, the restriction requirement was properly made under the unity of invention concept and it was shown that the apparatus is known in the prior art. Under PCT Rule 13.2, inventions disclosed

Art Unit: 1651

together in an applicant lack unity of invention when at least one of the inventions is known and does not provide a contribution over the art. Applicant's argument that unity of invention exists because the apparatus is used to carry out the claimed method is not persuasive because the restriction requirement properly showed and explained the lack of unity according to PCT Rule 13.2.

Regarding Applicant argument that classification was not made in the restriction, Applicant is reminded that classification of the inventions by US classification codes is not required by 35 USC 372. Addressing Applicant's assertions that distinctness and independence were not demonstrated in the restriction requirement and that the PTO did not show distinctness between the apparatus and the method of using said apparatus as discussed in the MPEP 806.05(e), Applicant is again reminded that the applications was properly restricted under 35 USC 372 which does not require an analysis of such factors. However, the inventions are independent and distinct as specified by MPEP 806.05(e) because the method can be carried out *without* the claimed apparatus. The claimed method can be accomplished with a simple dark-field microscope.

Applicant's argument regarding the species election is found persuasive and the specie election requirement is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-21 and 25-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/14/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1651

Claims 1-9 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2-5, 9, 22 and 23 are rejected because the claims recite one or more numbers in parentheses, i.e. "(22)". The purpose and meaning of these numbers is unclear because they do not appear to relate to any part of the claims. It is suggested that they be deleted.

Claims 1 and 22 are rejected because the phrase "characterizing a culture liquid" is vague. It is unclear what the object of the characterization is.

Regarding claim 1, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 1 and 22 are rejected because the phrase "microscopic imaging of the cells (22) and by evaluating the image" is vague. It is unclear if the "microscopic imaging" is an actual step of the method. Further, it is unclear how the microscopic imaging is related to the dark-field illumination in line 7 of claim 1 or part (a) of claim 22. The steps for the "evaluation of the image" is unclear. Further, the "image" lacks antecedent basis in the claim because there is no indication that the microscopic imaging results in an image.

Claims 1 and 22 are rejected because the phrase "the image evaluation comprises a comparison of the intensities of light output by the interior of the cell and by the edge of the cell, by means of which comparison living and dead cells are distinguished" is vague. The term "output" is unclear. When cells are illuminated, they reflect or scatter light. The term "output" implies that the cell is generating light on its own. The "intensities of light output" by the various parts of the cells lacks antecedent basis in each said claim because there is no step in the claim wherein light is reflected or scattered in response to illumination of the cells in culture.

Claims 1 and 22 are rejected because the phrases "by means of which comparison living and dead cells (22) are distinguished in order to determine the vitality of the culture liquid" (claim 1) and "wherein

Art Unit: 1651

the comparison allows the distinguishing of living and dead cells (22) in order to determine the vitality of the culture" (claim 22) are vague. It is unclear how the image evaluation relates to cell vitality. That is, what is it about the comparison between the "light output" from the various areas of the cell that relates to how one determines if the cells are dead or alive. The claims lack a step that allow one to make a conclusion regarding the cell vitality and the results of the image comparison.

Claims 2-9 and 22-24 are rejected because the phrase "characterized in that" is vague; it is not clear what characteristics are being considered. It is suggested that the phrase be changed to "wherein".

Claims 2-6 and 8 are rejected because the phrase "also carried out" is vague and indefinite. The phrase is unclear because it lacks steps to indicate what steps are being carried out. For example, in claim 2, the claim reads "a bright-field illumination is carried out" is unclear because the phrase does not indicate what steps are being accomplished with the bright-field illumination. It is unclear what the purpose of the bright-field illumination is.

Claim 2 is rejected because the term "apart from the dark-field illumination" is vague and indefinite. It is unclear if "apart" means at a separate time, in a physically separate space, or has some other meaning.

Claim 2 is rejected because the term "output" is unclear. When cells are illuminated, they reflect or scatter light. The term "output" implies that the cell is generating light on its own. The "intensities of light out" by the various parts of the cells lacks antecedent basis in the claim because there is no step in the claim wherein light is reflected or scattered in response to illumination of the cells in culture.

Claim 5 is rejected because the phrase "phase contrast" is unclear. Is the term intended to read as "phase contrast"?

Claims 6 and 24 are rejected because the phrases "differently polarized light" (claim 6) and "different polarizations" (claims 6 and 24) are vague and indefinite. It is unclear if the polarized light is generated by different means or if "differently" is related to a characteristic of the polarized light.

Art Unit: 1651

Claims 6 and 7 are rejected because the phrase "various types of illumination" lacks antecedent basis in claims 1 or 2. It is unclear to what the "various types" refer.

Claims 6, 7 and 24 are rejected because the phrase "with the aid of" is vague. It is unclear what type of aid is being given and there are no clear steps that demonstrate what the "aid" is or does.

Claim 23 is rejected because the phrase "further evaluated by at least one analysis selected from the group consisting of bright-field illumination..." is vague. The nature of the "evaluation" is unclear. The purpose of using the other types of illumination is not clear because there is no relationship established between their purpose in the method and determining cell vitality in a culture.

Allowable Subject Matter

The closest prior art neither discloses nor suggests a method of determining cell vitality in a culture by illuminating some portion of a cell culture on a dark-field and comparing the light reflected or scattered from the center of the cell and the edge of the cell and relating said comparison to cell vitality.

Korber et al. (1996) teach using digital image analysis and either dark-field, phase-contrast or confocal laser microscopy to measure bacterial plasmolysis as a physical indicator of cell viability. Analysis of the reflectance of light from the cell center and edge to determine cell vitality is not disclosed.

Cook et al. (US 6,438,396) disclose a method of imaging tissue with various types of illumination to provide images of sub-surface cell phenomena. However, cell vitality is not determined.

Cabib et al. (US 5,784,162) discloses the illumination of cells, detecting the reflectance and scattering of light from said illuminated cells. Collecting said data and storing said data in pixels. However, Cabib et al. do not teach using the collected data to determine cell vitality.


Bittner et al. (1998) teach *in situ* microscopy for on-line determination of physical parameters of cells. However, Bittner et al. do not teach the steps of determining cell vitality according to the claimed method.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JEAN C. WITZ
PRIMARY EXAMINER